

## **REMARKS**

The pending Office Action addresses and rejects claims 1, 2, 7-10, 13-20, 42, 43, and 46-50. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

### **I. Amendments to the Drawings**

Applicants submit herewith a replacement drawing for FIG. 3A. This replacement drawing corrects an error in the formal replacement drawings submitted on October 31, 2007 and is substantially identical to FIG. 3A as originally filed on March 31, 2004. No new matter is added.

### **II. Amendments to the Claims**

Applicants amend claims 1, 42, and 43 to recite that the fastening element is adapted to cause a male connector (claim 1), at least one connecting feature (claim 42), or at least one elongate member (claim 43) to *clamp* and engage a mating element. Support for this amendment can be found throughout the specification and drawings, for example in FIG. 1A and in paragraphs [0008] and [0033]-[0034]. Claim 18 is amended to correct a typographical error. Support for this amendment can be found throughout the specification and drawings, for example in paragraph [0027]. No new matter is added.

### **III. Claim Rejections Pursuant to 35 U.S.C. § 102(b) – “Yue”**

Claims 1, 2, 7-9, 13-16, 20, 42, and 43 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,536 of Yue (“Yue”). Applicants respectfully disagree.

#### **A. Claim 1**

Claim 1 recites, in part, a first elongate member having a female connector, a second elongate member having a male connector, a mating element adapted to extend through the male and female connectors, and a fastening element that is adapted to cause the male connector to *clamp and engage* the mating element.

Yue fails to teach or even suggest such a configuration. The Examiner argues that the side plate (2) of Yue forms the claimed first elongate member, that the blade portion (1) of Yue forms the claimed second elongate member, and that the worm gear adjustment portion (4) of Yue forms the

claimed fastening element. Although not explicitly stated in the Office Action, it appears that the Examiner relies on a pivot pin shown in FIGS. 1A-1C of Yue to form the claimed mating element.

There is no teaching in Yue that the worm gear adjustment portion (4) is capable of causing the blade portion (1) to *clamp and engage* the pivot pin. In fact, the pivot pin of Yue is never clamped at all. Yue thus lacks the claimed fastening element adapted to cause a male connector to clamp and engage a mating element.

Furthermore, as explained in detail in the Appeal Brief filed March 31, 2009, Yue lacks several other limitations of claim 1. Accordingly, claim 1 is not anticipated by Yue.

## B. Claims 42 and 43

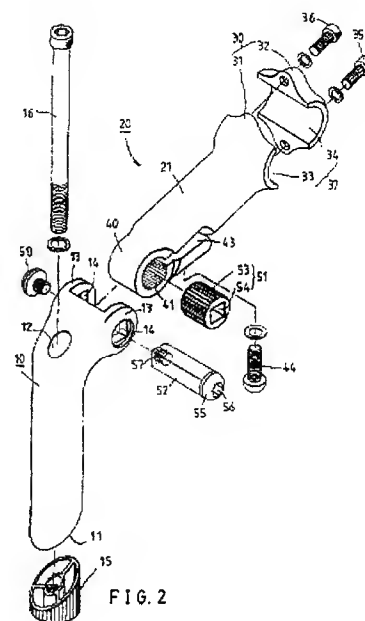
Claim 42 recites a fastening element adapted to cause at least one connecting feature to *clamp and engage* a mating element. Claim 43 similarly recites a fastening element adapted to cause at least one elongate member to *clamp and engage* a mating element. For the same reasons discussed above with respect to claim 1, Yue fails to teach or even suggest such a fastening element.

Accordingly, claims 1, 42, and 43 are not anticipated by Yue. Claims 2, 7-9, 13-16, and 20 are not anticipated by Yue at least because they depend from claim 1.

## IV. Claim Rejections Pursuant to 35 U.S.C. § 103(a) – “Lai & Carden”

### A. The Scope And Content Of The Prior Art

Lai discloses an adjustable bicycle handlebar tube as shown in FIG. 2, which is reproduced herein, having a head tube (10) with two circular lugs (13) formed on one end, and an upright tube (20) with a pivoting portion (40) adapted to be disposed between the circular lugs (13) for mating the upright tube (20) to the circular lugs (13). The angle between the head tube (10) and the upright tube (20) is adjusted using a braking member (51) that is adapted to fit within a hole (41) formed in the pivoting portion (40) of the upright tube (20) before the upright tube (20) is disposed between the lugs (13), so that when the tube (20) is



disposed between the lugs (13), a hole (54) of the braking member (51) is aligned with two holes (14) that extend through the lugs (13). A shaft (52) is then inserted into the hole (54) and the two holes (14) formed in the lugs (13). A bolt (58) is coupled to the shaft (52) to lock the head tube (10) in relation to the braking member (54). To lock the head tube (10) in relation to the upright tube (20), another bolt (44) is inserted through a portion of the upright tube (20) to cause serrated edges of the hole (41) and the braking member (51) to engage with one another.

Carden discloses a matrix alloy composite that includes a base material metal, a boron or silicon carbide, a reinforcing agent, and at least one metal having an intermetallic phase temperature lower than the melting point of the base material metal.

### **B. The Examiner's Rejection**

Claims 1, 2, 7, 10, 13-20, 42, 43, and 46-50 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,509,328 of Lai in view of U.S. Patent No. 6,284,014 of Carden. The Examiner argues that Lai discloses a first elongate member (10) having a female connector with opposed arms (13), and a second elongate member (20) having a male connector (40) that is adapted to mate to the female connector, as shown in FIG. 2 above. The Examiner asserts that the members (10, 20) are adjustably coupled to one another, and that a fastening element locks the elongate members (10, 20) in a fixed position. The Examiner also argues that the device includes a bore (14) extending through the opposed arms on the female connector and through the male connector, and a central mating element (51, 52) extends through the bore for mating the male and female connectors together.

The Examiner acknowledges that Lai fails to disclose a device that is biocompatible, and instead argues that it would have been obvious to form the device of Lai from the alloy composition taught by Carden such that it would be biocompatible. *See Office Action* at 6. The Examiner further asserts that the screws (35, 36) of Lai are anchors that are capable of being secured to the spine.

### **C. The Claimed Invention Is Not Obvious Over Lai And Carden**

Independent claims 1, 42, 43, and 46 each recite a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members. The Examiner argues that the screws (35, 36) of Lai are anchors that can be secured to the spine. The screws (35, 36) are

used by Lai to form a portion of the upright tube (20), and specifically are used to couple two fastening heads (31, 32) together. Due to the orientation of the screws, it would be impossible to use the screws to attach the device to a spine. Moreover, Lai does not teach or even suggest that the screws (35, 36) are spinal anchors that are implantable in bone and configured to mate to at least one of the first and second elongate members, as required by independent claims 1, 42, 43, and 46. Lai is directed to a bicycle handlebar design, and does not ever mention spinal anchors or anything else implantable in bone. A spinal anchor is a term known to a person having ordinary skill in that art, and would not be understood to include any type of screw that can be used for any application, such as a screw used to secure components of a bicycle handlebar.

Independent claims 1, 42, 43, and 46 also each recite that at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod. The term “spinal fixation rod” is well known to a person having ordinary skill in the art, and that certainly would not be understood to refer to just any type of rod, such as a tube of a bicycle handlebar. In addition, the bicycle handlebar of Lai is not biocompatible, and Lai does not teach or even suggest forming the handlebars from any type of material that is compatible with living tissue. The Examiner asserts that it would have been obvious to form the handlebars of Lai from the titanium alloy composite of Carden “in order to make the device stronger, more rigid, and lighter.” *Office Action* at 6. Applicants note however that there is no teaching in Carden that the titanium alloy composite disclosed therein is biocompatible. While the Examiner points to a passage indicating the suitability of the Carden material for medical applications such as “prosthesis, braces, medical instruments and tools,” there is no teaching of its suitability for implantable medical applications for which biocompatibility is essential. Applicants note that the American Society for Testing and Materials (ASTM) recognizes 38 different grades of titanium alloy, not all of which are biocompatible and/or suitable for implantation. Thus, it would not be obvious based on the teachings of Lai and Carden to make the upright tube (20) or head tube (10) of Lai from a biocompatible material.

Finally, Lai is non-analogous art and therefore cannot be relied on to reject the pending claims as obvious. In order to rely on a reference in analyzing the obviousness of the subject matter at issue, the reference must be analogous prior art. A reference is “analogous” if (1) the reference is within the field of the inventor's endeavor, or (2) the reference is reasonably pertinent to the particular problem with which the inventor was involved.

Lai is not within the field of Applicants' endeavor. Lai is directed to bicycle handlebars. The present invention, on the other hand, is directed toward implantable devices and methods for spinal fixation. No person having ordinary skill in the art would rely on a reference directed toward *a bicycle handlebar* to form a device for *spinal fixation*. These are distinct fields with vastly different design objectives and considerations.

Lai is also not reasonably pertinent to the problem with which Applicants were involved, namely, developing improved spinal fixation methods and devices. Applicants refer the Examiner to MPEP § 2141.01(a) and *In re Clay*, 966 F.2d 656, 659 ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.") The subject matter of Lai would not have logically commended the attention of an inventor of the claimed subject matter, since no inventor working in the area of spinal fixation would logically look to bicycle parts to solve a problem. Further, MPEP § 2141.01(a)(IV) includes examples of analogy in the mechanical arts. For example, in *In re Oetiker*, 977 F.2d 1443),

Applicant claimed an improvement in a hose clamp which differed from the prior art in the presence of a preassembly "hook" which maintained the preassembly condition of the clamp and disengaged automatically when the clamp was tightened. The Board relied upon a reference which disclosed a hook and eye fastener for use in garments, reasoning that all hooking problems are analogous. The court held the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments.

Like the above-referenced case, while the Examiner may argue that Lai is analogous because it includes an adjustable connection, an inventor seeking to solve a problem regarding spinal fixation would not be reasonably be expected or motivated to look to a bicycle part in solving that problem. Accordingly, the bicycle handlebars of Lai are not within the field of the inventors' endeavor, nor are they reasonably pertinent to the problem with which the inventors were involved. Lai is therefore non-analogous art and reliance thereon is inappropriate.

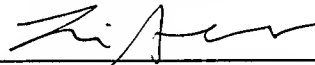
Accordingly, claims 1, 42, 43, and 46 distinguish over Lai and Carden, taken alone or in combination, and represent allowable subject matter. Claims 2, 7, 10, 13-20, and 47-50 are allowable at least because they depend from allowable claims 1 and 46.

**V. Conclusion**

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicants' amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Date: November 4, 2009

Respectfully submitted,



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